



Job Description: Quality Control (Analytical) Trainee

Primary Objectives of the Job:

This position is required perform all tasks associated with the QC analytical lab operations which include chemical analysis, biochemical analysis, equipment calibration/maintenance, records review, records approval, deviation/investigation write up/review, equipment qualification, method validation, method transfer and other tasks as assigned.

Primary Responsibilities Include:

Core Responsibilities:

- Complete 8 Core Modules together with elective modules in Biologics conducted in Singapore Polytechnic and On-the-Job Training (OJT) with Takeda
- Perform chemistry, biochemistry analysis of in-process samples, bulk drug substance (BDS), non-routine samples, water samples, rinse samples and raw material testing.
- Ensure tests assigned are performed in a timely manner in compliance to Standard Operating procedures
- Perform equipment calibration and maintenance.
- Perform review/approval of QC records/ logbooks.
- Perform trending of lab results.
- Initiate and participate in Out Of Specification (OOS), Invalid test and Lab Deviation Investigation Write-Up and assist in timely closure of laboratory invalid results, lab investigation and CAPA.
- Write/revise SOPs, forms, training qualifications (TQ) and risk assessments (RA).
- Provide technical support to QC Personnel in laboratory related troubleshooting e.g. lab equipment failure, method
- Participate in method validation/ transfer or equipment qualification when necessary
- Ensure proper, safe handling and disposal of waste; ensuring a safe working environment.

General Responsibilities:

- Carry out 5S and ensures good housekeeping of Analytical Lab area.
- Support and participates in Operation Excellence initiatives (such as GEMBA and GMP walk).
- Participate in projects towards improving safety performance and continuous improvement initiatives.
- Assist Supervisor to support internal and external compliance audits.
- Responsibility to adhere to any applicable EHS requirements.
- Commitment to a fair and respectful relationship to others and behavior in accordance with Takeda's Code of Conduct.
- Any other duties as assigned by supervisor.

Education and Experience Requirements



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- Bachelor Degree in Chemistry, Biochemistry, Biotechnology or equivalent, preferably with more than 1 year of experience in Pharmaceutical, Biopharmaceutical or related manufacturing environment.
- Demonstrated ability to collaborate with cross functional or cross sites to achieve objectives.

Key Skills and Competencies

- Project Management Skills
 - Organization and planning skills
 - Analytical and Logical thinking skills
 - Ability to work and collaborate within the team
- Technical Skills
 - Basic GMP knowledge
 - Knowledge in Microsoft Office.
- Problem solving
 - Basic problem solving skill